Dockets Management Branch (HFA-305)
Food and Drug Administration
5630 Fishers Lane, rm. 1061
Rockville, Maryland 20852

Re: Docket No. 98N-1265

The 12/23/98 *Draft Memorandum of Understanding on Interstate Distribution of Compounded Drug Products*, in its current form, threatens access to important medications for some persons with AIDS and other illnesses.

Last November *AIDS Treatment News* investigated a serious shortage of FDA-approved injectable testosterone, apparently the unintended result of an FDA enforcement action against a manufacturer (see "U.S. Testosterone Shortage: Call for Information," *AIDS Treatment News* #306, and "Testosterone Cream and Gel Available; Prices Vary Widely," Issue #307; both are available at www.aids.org/atn). Many patients and physicians were unable to obtain the products they had been using, or a suitable equivalent. As one alternative, we investigated compounded testosterone cream or gel for topical use. We found a more than 10-fold difference in price, and fortunately were able to locate a reliable compounding pharmacy (not in our state, however) which could supply these products for $20 per month.

The 20% ceiling on out-of-state shipment of a compounded drug (in the 12/23/98 *Memorandum of Understanding*) is likely to make reliable products much harder to obtain. This figure is not included in legislation, and was apparently picked arbitrarily. It will mean that patients will rely on less experienced compounders, or will need to travel to other states to obtain their medication.
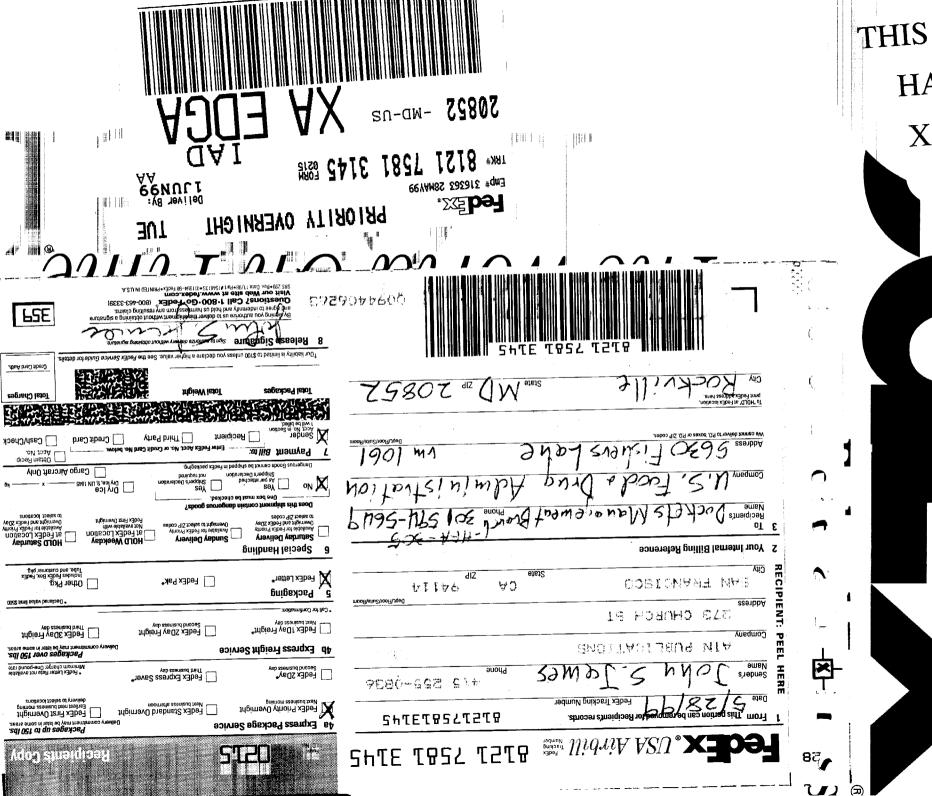
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A "memorandum of understanding with the FDA that addresses the interstate distribution of inordinate amounts of compounded drug products" does not require an arbitrary ceiling or other provisions which will make it difficult for patients to obtain necessary care.

Sincerely yours,

John S. James
Editor and publisher, *AIDS Treatment News*

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